Oral Statement of
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Mr. Chairman and members of the Committee, my name is James Christian and I am Vice President and Head of Global Corporate Security for Novartis International AG ("Novartis"). Prior to joining Novartis, I spent 20 years with the United States Secret Service, the last five as a Special Agent in Charge. While in Government service, one of my duties was to suppress the international counterfeiting of U.S. currency. At Novartis, for the last 16 years, one of my responsibilities is to oversee the company's worldwide anti-counterfeiting operations.

In the past several years, Novartis has participated with law enforcement and health authorities in over 200 counterfeiting investigations in 33 countries and involving hundreds of drug products. I have witnessed firsthand the virtually limitless ingenuity and resourcefulness that unlawful enterprises utilize to manufacture and distribute ineffective and often unsafe

counterfeit products. I have also witnessed the hardship and misery counterfeit medicines bring to patients and their families. There can be no doubt that drug counterfeiters present a severe and growing threat to the health and safety of U.S. citizens.

Novartis has a compelling interest in protecting the medicines that it currently markets as well as those now under development. This year alone, Novartis will spend more than $4.2 billion on drug research and development. More importantly, patients using Novartis products must have every confidence that the drugs are safe and effective.

Counterfeit drugs are "fake" medicines, produced and packaged to look like the genuine article. They include products containing correct ingredients, although they may be adulterated or in the wrong dosage strength; incorrect ingredients; no active ingredient; or an insufficient quantity of active ingredient; and usually have phony packaging and labeling. Counterfeit drugs may be made in garages, basements, or warehouses, often under horrific conditions.

Counterfeiters are able to produce labels that are virtually indistinguishable from the authentic materials. They can also make and stamp tablets with company logos and put them in special packaging such as blister packs.

We have scores of examples of counterfeit, expired, and adulterated medicines. In one case, our anti-counterfeiting efforts interdicted millions of yellow tablets of a popular pain killer that were virtually indistinguishable from the genuine product – including the company logo. These tablets were made of boric acid, floor wax, and lead-based yellow paint used for road markings. Sacks of these "raw materials" were stacked throughout the counterfeiters' ramshackle warehouse in Bogata, Columbia.

Production of counterfeit medicines is pervasive outside the United States and is growing at an alarming rate. We can provide the Committee with detailed information on the extent of counterfeiting activity in Latin and Central America, Asia, Russia, China, and India. First, let's look at a Novartis manufacturing facility, and then a counterfeit manufacturing plant.

Russia is a drug counterfeiter's paradise. Politically connected organized crime elements in that country face little resistance from the government, and the laws and penalties for counterfeiting pharmaceuticals are weak or non-existent. With its recent expansion, the European Union's border in the East is no longer the well-controlled German border but instead is the more porous Polish border. Once counterfeit drugs have crossed into Poland, they have virtually unobstructed access to the markets in France, Germany, Spain, and the rest of the European Union countries. These counterfeit drugs, which have passed through nations in the European Union, could easily find their way to pharmacy shelves in the United States. Indeed, some counterfeit Russian pharmaceuticals have already been discovered in this country. Europe has also developed an internet sales problem, with hundreds of web sites selling counterfeit medicines, often from China.

Counterfeiting is also a burgeoning problem in China where seizures have secured large quantities of fake drugs. Novartis and other pharmaceutical companies participated in a raid with authorities in Shantou that resulted in the seizure of over 1800 cartons of counterfeit pharmaceutical products from 14 multinational companies. What is unique about counterfeiting in China is that many of the counterfeiting operations are

publicly traded, and often have health, regulatory, and law enforcement officials as shareholders. More recently, Novartis has become aware of a Hangzhov-based website called Alibaba (www.alibaba.com) where major players in an underground counterfeiting network surface to buy and sell counterfeit products including prescription drugs.

In Latin America, the counterfeiting problem is staggering. Last November, it was determined that four children died from counterfeit drugs at the Jose Maria Cabral y Baez Hospital in the Dominican Republic. In Venezula, six children are known to have died from counterfeit drugs, including counterfeit anesthesia in 2004. Six months ago, in Argentina, Veronica Diaz, suffered acute liver failure and died after being injected with a counterfeit iron supplement while hospitalized. A review of the hospital records disclosed that two other women had died after being injected with the same product.

Two months ago police in Lima, Peru seized four tons of adulterated and counterfeit pharmaceuticals, including ampoules for injection which contained feces and dangerous bacteria. These seizures took place after numerous epileptic and diabetic patients were hospitalized after taking counterfeit medicines.

In Colombia, the length and breadth of the counterfeiting problem is mind boggling. Novartis alone is responsible for the seizure of a counterfeit lab every month. The problem is referred to as "El Otro trafico de drogas", or "The other drug trafficking". Many hospital administrators have no faith in the drugs in the hospital pharmacy, and efforts to switch suppliers are often met with threats of violence.

Pharmaceutical companies and non-U.S. law enforcement authorities have an extremely difficult time suppressing international counterfeiting operations. Many counterfeit pharmaceuticals are manufactured so cleverly that it is virtually impossible for consumers, government officials, and law enforcement agencies to identify them as counterfeit without elaborate testing. Detection is made more difficult by the criminal practice of mingling counterfeit, adulterated, expired, stolen, and genuine product. When this occurs, random or sample testing is totally ineffective. Counterfeiters do not care about the quality and safety of the product. Their goal is to sell a fake drug to an unsuspecting patient.

The United States relies on foreign countries to protect American citizens from counterfeit medicines. This reliance is misplaced. Many governments lack the interest, resources and technological sophistication needed to address the problem.

While certain overt and covert technologies may improve the distribution system and increase a manufacturer's ability to manage the supply chain and to track and trace products, no one has yet demonstrated the ability of such technology to protect against counterfeiting.

New anti-counterfeiting technologies have numerous shortcomings including the following:

- In almost every case, the technology, be it a hologram, tamper proof labels, embossing, thermo-reactive ink, RFID tags, DNA markers, and the like, enable companies to track cardboard, not product. It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging.

- In the United States and in the European Union, the two largest pharmaceutical markets in the world, repackaging is legal; thus, without violation of any law, packaging, with all types of expensive, state of the art secure devices, can end up in the trash or worse, in the hands of a counterfeiter, while genuine product is legally distributed in packaging with no security features.

- RFID technology which was featured in a FDA task force report is more of an inventory management tool than an anti-counterfeiting device.

    - A counterfeiter or diverter could purchase RFID tags and attempt to mimic manufacturers' RFID codes.

    - Industries which have and are using RFID products have noted that when their products enter the "grey market", their RFID tags are often "zapped" rendering them unreadable.

    - Counterfeiters generally deal, not only with counterfeit product, but with diverted, expired, and stolen product as well. Envision

the scenario where a counterfeiter steals product, removes genuine product from the "secure packages", and then puts the counterfeit product in these packages, and then reinserts the counterfeit product back into the system. The counterfeit product would pass through all the readers successfully. What then happens to the genuine product? The irony is that the genuine product would most likely be repackaged in counterfeit packaging with unreadable tags and entered into the distribution system. If the RFID system works correctly, the genuine product would be kicked out of then system, but later determined to be genuine, undermining any confidence in the system.

Where do we go from here? Now is the time to do a realistic assessment of the problem. In my view there is no quick fix. There is no "solution" on the horizon. If we place our trust in the hope that a "solution" will be available in the near future, we may well neglect to take the incremental steps necessary to make progress against the terrible plague of counterfeit medicines.

I cannot say strongly enough that drug counterfeiters, blackmarketeers, and other organized criminal elements are ready, willing, and able to exploit any perceived weakness in the U.S. pharmaceutical system. Make no mistake, drug counterfeiting severely imperils public health and safety across the globe, including the United States. Now is the time to strengthen our commitment to keeping our medicines the best and safest in the world.

Thank you.